

REMARKS

These amendments and remarks are being filed in response to the non-final Office Action mailed August 19, 2010 (the “Office Action”). Although no fees are believed due, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 14-1437.

At the time of the Office Action, claims 1-5 and 7 were pending. In the Office Action, all claims were rejected under one or more of 35 U.S.C. §112, second paragraph and 35 U.S.C. §103(a). By this Amendment, claims 1, 5, and 7 are amended and claims 8 and 9 are added. Support for the amendments can be found throughout the specification. *See, e.g.*, Specification, Paragraph [0007]. No new matter is added.

The amendments presented herein have been made solely to expedite prosecution of the instant application to allowance and should not be construed as an indication of Applicant’s agreement with or acquiescence to the Examiner’s position. Accordingly, Applicant expressly maintains the right to pursue broader subject matter through subsequent amendments, continuation or divisional applications, reexamination or reissue proceedings, and all other available means. The rejections and responses thereto are set forth fully below.

Claim Rejections - 35 USC § 112

In the Office Action, claims 1-5 and 7 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner noted a lack of sufficient antecedent basis for various limitations recited in claims 1, 5, and 7. Appropriate corrections have been made to claims 1, 5, and 7. Accordingly, Applicants respectfully request that the rejection based on 35 U.S.C. §112, second paragraph, be withdrawn.

Claim Rejections – 35 U.S.C. § 103(a)

In the Office Action, claims 1-5 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Canadian Patent No. 2,335,149 issued to Golz-Berner *et al.* (hereinafter “Golz-Berner”) and European Patent Publication No. EP 0707844 A2 to Burmeister *et al.* (hereinafter “Burmeister”) in view of PCT Patent Publication No. WO 00/64472 to Murad, H. (hereinafter “Murad”), Japanese Patent Publication No. JP11060496 to Souma *et al.* (hereinafter “Souma”), Japanese Patent Publication No. JP11263718 to Fujimura *et al.* (hereinafter “Fujimura”) and Japanese Patent Publication No. JP61289010 to Hiroaki *et al.* (hereinafter “Hiroaki”).

The Office Action asserts that Golz-Berner and Burmeister disclose all elements of the claims with the exception of extracts from figs, pomegranate, rosemary and peeled musk melons. The Office Action then asserts that these ingredients can be found in the secondary references. Applicant respectfully disagrees, in part because the cited references fail to disclose several substantial claim elements and in view of the substantial unexpected results produced by the claimed cosmetic. In support of these arguments, Applicant refers to the Declaration on Co-Inventor Karin Golz-Berner Under 37 C.F.R. § 1.132 submitted on July 16, 2009 (hereinafter “Golz-Berner Decl. 2009”) and submits herewith a second Declaration on Co-Inventor Karin Golz-Berner Under 37 C.F.R. § 1.132 (hereinafter “Golz-Berner Decl. 2011”).

Prior to addressing the cited references, Applicant will review the claimed subject matter as set forth in amended claim 1, which recites:

1. (currently amended) An anti-ageing skin cosmetic comprising:
 - 0.1 to 5% by weight of an extract from a mixture of fig leaves and fruits;
 - 0.1 to 3% by weight of an extract from pomegranate fruits;
 - 0.001 to 0.5% by weight of a ground dry mixture of rosemary stems and leaves;
 - 0.01 to 3% by weight of liposomes containing an extract from peeled musk melons;
 - 0.1 to 5% by weight of liposomes containing a plankton extract containing ~~the~~ a photolyase enzyme;

0.1 to 5% by weight of liposomes containing 0.1 to 0.5% by weight, in relation to the liposome weight, of a micrococcus lysate containing the a UV-endonuclease enzyme; and

up to 100% by weight, other active substances, carrier substances, adjuvants or mixtures thereof, all percentages being relative to the cosmetic's total weight.

The claimed subject matter is drawn to an anti-ageing skin cosmetic. The cosmetic contains the claimed amounts of each ingredient, including an extract from a *mixture of fig leaves and fruits*, an extract from pomegranate fruits, a ground dry mixture of rosemary stems and leaves, *liposomes* containing an extract from *peeled musk melons*, liposomes containing a plankton extract containing a photolyase enzyme, and liposomes containing a micrococcus lysate containing a UV-endonuclease enzyme. When these elemental ingredients are included in the unique combination claimed, and not interfered with by other elemental ingredients, the result can be the claimed cosmetic having a synergistically enhanced effect on the reduction of fine wrinkles compared to any fine wrinkle reduction exhibited by the claimed ingredients individually. (Golz-Berner Decl. 2009). As explained in the Specification: “The anti-ageing skin effect to be expected from the inventive anti-ageing skin cosmetic due to some of its constituents is by far exceeded by an overall synergistic effect.” Specification, Paragraph [0014].

Turning to the cited art, Soma is drawn to a medicine for enhancing the ability of keratinocyte from human skin to produce hyaluronic acid by including a plant extract from one or more plants selected from the group comprising plants belonging to the genera Morus, Artocarpus, Broussonetia, and Ficus (e.g. *Morus alba* and *Ficus carica*), preferably at 0.005-5 wt.% based on dry weight of the medicine. (Soma English Abstract). Attached hereto as Exhibit A is a mechanical translation of Soma. As it is shown in Exhibit A, Soma describes the plant extract from the genus Ficus as follows: “As vegetation belonging to Ficus (*Ficus*), fruits of fig [fig] (*Ficus carica L.*), a leaf and a stem of . . . (*Ficus pumila*), a stem, a branch, etc. are mentioned.” As such, the Soma reference discloses only an extract of the **fruits** of the *Ficus carica* fig.

In contrast, the claimed cosmetic requires 0.1 to 5% by weight of an extract from a mixture of fig leaves and fruits (claim 1). As explained in the Specification:

The fig extract used is an extract consisting of a mixture of leaves and fruits of the *Ficus carica* fig, wherein the two constituents can be contained in a ratio of 25-75:75-25. . . . The fig extract contains effective amounts of the proteolytic ficin enzyme and contributes to cell regeneration.

Specification, Paragraph [0007]. Attached hereto as Exhibit B is an excerpt from the scientific encyclopedia Die große Enzyklopädie der Arzneipflanzen und Drogen (The Big Encyclopedia of medical Plants and Drugs), Heidelberg 2003. As it is shown in Exhibit B, the ficus fruit contains carotinoids, chlorophylls, lipids, vitamins (B1, B2, C, nictinamide), flavinoits, etc.; while ficus leaves contain coumarins, furanocoumarins, psoralen, bergapten, umbelliferon, marmesine, scopolectine, etheric oil, polysaccharides, vitamin C, triterpenes and in the latex of the leaves the enzyme ficin. (Exhibit B, p. 321.) As such, an extract from fig fruit alone would not include the enzyme ficin and would be clearly distinguishable from an extraction from a mixture of fig leaves and fruit. Thus, Soma fails to disclose the claimed extract from a mixture of fig leaves and fruits.

Hiroaki is drawn to a cosmetic obtained by incorporating an extract component obtained by extracting the whole herb of a cucurbitaceous plant, particularly. dishcloth gourd or melon, *i.e.* leaves, stems or roots, with water or a water-soluble solvent. (Hiroaki English Abstract). As such, the Hiroaki reference discloses an extract of the **whole** melon.

In contrast to Hiroaki, the claims are drawn to 0.01 to 3% by weight of liposomes containing an extract from peeled musk melons (claim 1). As explained in the Specification:

The extract from the musk melon *Cucumis melo*, which is obtained from melons whose outer peel has been removed, using water at a temperature of 10-30° C, helps to reduce the transepidermal water loss (TEWL) and is advantageously incorporated in the cosmetic via liposomes whose outer shell consists of phospholipids and olive oil.

Specification, Paragraph [0010]. Applicant conducted tests comparing a serum of Example 1 without liposomes but with 0.1% by weight of a conventional extract of unpeeled melon with the

/

serum of Example 1 containing 0.1% by weight liposomes with the extract of peeled musk melon. *See* Golz-Berner Decl. 2011. The test results indicate a significant improvement in the moisturizing effect of the claimed cosmetic versus a product substituting an extract of unpeeled melon. *See id.* As such, an extract of whole, *i.e.* unpeeled, melon would be clearly distinguishable from an extract of unpeeled melon, and even more so from liposomes containing an extract of unpeeled melon. Thus, Hiroaki fails to disclose the claimed extract from peeled musk melons encapsulated within liposomes.

Neither Soma nor Hiroaki, whether alone or in combination, disclose or suggest the claimed combination of 0.1 to 5% by weight of an extract from a mixture of fig leaves and fruits and 0.01 to 3% by weight of liposomes containing an extract from peeled musk melons, in addition to the other claimed ingredients, to provide an enhanced anti-ageing skin effect. These deficiencies are not corrected by any of the other cited references. In addition, absent impermissible hindsight, there is no motivation or suggestion in the cited references, or elsewhere, that would lead to the claimed invention.

The claimed cosmetic includes four different plant extracts and two different substances (enzymes) in specific amounts and results in a product with synergistic effects. The cited references offer the following: Golz-Berner – 2 plants; Burmeister – 9 substances; Murad – 13 plants; Souma – 10 plants; Fujimura – 6 plants; and Hiroaki – 2 plants. A person of skill in the art with the aim of producing a cosmetic composition with improved anti-aging and improved moisturizing effects would have to select from *at least* those 42 plants a combination that would show the synergistically enhanced effect of the claimed cosmetic. The selection would involve numerous variables, including the type of plants and plant species, the parts of the plants (*e.g.* root, stem, fruit, etc.), the extraction agent(s), and the extraction temperature. Differences in each of the selected variables could lead to different results, including weaker anti-aging effects and side effects. None of the cited references provide any suggestion or motivation to combine the teachings of the cited references to arrive at the claimed cosmetic with its four plant extracts and two enzymes in the claimed amounts.

Furthermore, the Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *See In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); *In re Ackermann*, 444 F.2d 1172, 1176 (CCPA 1971); MPEP § 2145. For example, in *In re Chupp*, the claims were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and corn, but average results for other crops. 816 F.2d at 644. The prior art was a homolog of the claimed compound and was disclosed as being a selective herbicide for crops generally. The Federal Circuit found that superior activity in the specific application of the claimed compound to corn and soybeans was a “new and unexpected property.” *Id.* at 645. In *In re Corkill*, the Federal Circuit granted patentable weight to the “greater than expected result” of superior cleaning performance by the claimed combination of known detergents, certain zeolites, and an auxiliary builder, when a lesser performance was expected from the addition of the auxiliary builder. *See* 771 F.2d 1496, 1501-02 (Fed. Cir. 1985).

Analogously, as mentioned above, the claimed cosmetic unexpectedly produces synergistically enhanced anti-aging effects and moisturizing effects. Specification, Paragraph [0014]. The additive anti-aging skin effect to be expected from the individual constituents disclosed by the references is far exceeded by the overall synergistic effect produced by the claimed combination of ingredients in the claimed amounts. Specification, Paragraph [0014].

This superior effect was clearly new and unexpected, as demonstrated by the test results described in Example 3 of the Specification and the Golz-Berner Declarations. Specifically, the Specification noted:

It was particularly surprising that 96% of the test persons were able to note an immediate effect after 1-2 days and that the effect was clearly noticeable in a high percentage of the participants after 1 week.

...
79% [judged] that there was a “long-term moisturizing effect” . . . These results prove an excellent moisturizing effect and a very good anti-ageing effect.

Specification, Paragraphs [0038] – [0041].

/

In the Golz-Berner Decl. 2009, Dr. Golz-Berner discussed the unexpectedly superior effect of the claimed cosmetic and submitted test results demonstrating a substantial improvement in the anti-aging effect compared to the Golz-Berner reference. In order to demonstrate the synergistic improvement in reduction of fine lines produced by the claimed cosmetic, consumer studies were conducted comparing a Group 1 which applied the claimed cosmetic of Example 1, a Control 1 group which applied the highly active composition disclosed in the Golz-Berner reference, and a Control 2 group which applied an anti-ageing skin cosmetic containing only the rosemary powder and pomegranate extract from the Example 1 composition. The percentage of consumers experiencing a reduction in fine lines for each of these groups was:

	Group 1	Control 1	Control 2
After 1 week	76%	33%	8%
After 2 weeks	81%	43%	17%
After 3 weeks	83%	45%	17%

Golz-Berner Decl. 2009, Section 4. Specifically, Dr. Golz-Berner noted:

From this it is clear that the compositions of Golz-Berner exhibited an RPF that exceeds most other skin care compositions. Thus, a substantial improvement in reduction of fine lines over Golz-Berner, such as that produced by the claimed anti-ageing skin cosmetic, is indeed an impressive and unexpected result.

...
Clearly, both Controls fall far short of the fine line reduction produced by the claimed anti-ageing skin cosmetic of Example 1.

...
Clearly, there is a synergistic effect produced when each of the claimed ingredients is combined with the others. This synergistic effect simply is not present when the ingredients are not used together. Furthermore, the magnitude of the increased reduction in the presence of fine lines over the composition used in Control 1 is particularly impressive considering the RFP values reported in the Golz-Berner reference.

Id.

In the Golz-Berner Decl. 2011, Dr. Golz-Berner submitted additional test results further demonstrating the unexpectedly superior anti-aging and moisturizing effects of the claimed

/

cosmetic. In order to further demonstrate the synergistic improvement in reduction of fine lines produced by the claimed cosmetic, a consumer study was conducted with 12 test persons applying six different serums for three weeks. The six serums contained the same basic serum in addition to the following:

- Serum 1 (S1): all remaining ingredients in accordance with Example 1
- Serum 2 (S2): Fig extract 0.5
- Serum 3 (S3): Pomegranate extract 0.5
- Serum 4 (S4): Rosemary powder 0.001
- Serum 5 (S5): Melon liposomes 0.1
- Serum 6 (S6): Photosomes & Ultrasomes 0.2

The participants applied the serums 1 – 6 on areas of their faces, necks or decolletés twice a day. Digitalized images of the sites were made at preset intervals of one week and evaluated according to the number and depth of wrinkles using a computer program. The results are shown in the following table:

Reduction of wrinkles [%]						
after	S 1	S 2	S 3	S 4	S 5	S 6
1 week	44	5	4	3	0	14
2 weeks	52	9	10	6	2	19
3 weeks	58	8	9	7	2	22

The results show the significant synergistic effect of the combination of all individual actives. In the absence of a synergistic relationship between the claimed ingredients, it would be expected that the percentage of reduction of wrinkles for the claimed cosmetic (S1) would be equal to the sum of the percentages of reduction of wrinkles for the remaining serums (S2+S3+S4+S5+S6). According to the 1 week data, the percentage of reduction of wrinkles for the claimed cosmetic was 44% while the sum of the percentages for the remaining serums was

only 26%, clearly demonstrating a synergistically enhanced effect. Accordingly, Applicants respectfully submit that the unexpected results overcome any *prima facie* case of obviousness that may be established by the cited references.

In summary, the cited references (i) do not disclose or suggest a cosmetic that includes 0.1 to 5% by weight of an extract from a mixture of fig leaves and fruits; and (ii) do not disclose or suggest a cosmetic that includes 0.01 to 3% by weight of liposomes containing an extract from peeled musk melons. Additionally, **the claimed cosmetic exhibits a superior anti-aging skin effect, which is a new and unexpected property that overcomes any prima facie case of obviousness.** For at least the foregoing reasons, Applicant respectfully submits that the combination of Soma, Fujimura, and Hiroaki fails to disclose or suggest each element of the claimed cosmetic of claim 1. Accordingly, Applicant respectfully requests that the above rejections be withdrawn.

Conclusion

For at least the reasons set forth above, the independent claim is believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned (561-847-7806 – direct line) if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

NOVAK DRUCE + QUIGG LLP

/Michael P. Byrne/

Date: January 18, 2011

Gregory A. Nelson, Reg. No. 30,577
City Place Tower
525 Okeechobee Blvd., Fifteenth Floor
West Palm Beach, FL 33401
Michael P. Byrne, Reg. No. 54,015
300 New Jersey Ave, NW
5th Floor
Washington, DC 20001

Docket No. 3975-039

Phone: (561) 847-7800
Fax: (561) 847-7801